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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,714	04/27/2007	Anders Carlsson	D7873.0003	5273

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EXAMINER	
MILLIGAN, ADAM C	
ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
12/17/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/597,714	CARLSSON ET AL.	
	Examiner	Art Unit	
	ADAM MILLIGAN	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-7,9-12,14,15,17-19,21-25,27,28 and 33-35* is/are pending in the application.

4a) Of the above claim(s) *24,25,27 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-7,9-12,14,15,17-19,21-23 and 33-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1pg(6/27/2009)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/26/2010 has been entered.

Applicants' arguments, filed 5/26/2010, have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claims 1-3 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herslof (WO 03/068267 - see PTO-892 dated 4/22/09).

Herslof teaches a composition which may be rectally administered as a suppository to deliver a pharmaceutical agent (p.1, lines 5-8). The suppository may comprise lipids from oats (p.6, lines 19-24), galactolipids (such as digalactosyldiglycerol, DGDG at p.6, lines 12-16), glycerol (p.7, lines 16-21), water (pg 7 lines 16-19), and triglycerides (p. 6, lines 27-30for the treatment of conditions amenable to said treatment (Claim 35).

Herslof does not teach the instantly claimed components as a single disclosed preferred embodiment.

It would be obvious to one of ordinary skill in the art to pick and choose among the components disclosed by Herslof to include in the rectally administrable pharmaceutical composition because the components are taught to provide an advantageous form of rectal delivery of a pharmaceutical agent.

Claims 1-3, 5-7, 9-12, 14, 15, 17-19, 21-23, and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klaschik et al (Constipation, Modern laxative therapy Support Care Cancer Vol. 11,

Pages 679-685, 2003) in view of Herslof (WO 03/068267 - see PTO-892 dated 4/22/09) and Tomaru et al. (Colonic Giant Migrating Contractions Induced by Glycerol Enema in Anesthetized Rats - Japan. J. Pharmacol. Vol. 63, Pages 525 -528, 1993).

Klaschik teaches the rectal administration of a glycerol tablet in order to treat constipation (pg 683, Column 2, Rectal Laxatives). Klascheck teaches that glycerol and olive oil are known rectal laxatives and may also be administered in the form of enemas, clysmas, or suppositories (Id.) Clysmas contain a combination of secretagogue-acting agents or stool softeners for rectal application (id). Enemas are the application of larger amounts of fluid into the rectum (id). The effect of the enema depends upon the amount of fluid applied (id).

Klaschik does not teach enemas the addition of lipids.

Herslof teaches a composition which may be rectally administered as a suppository (e.g. p.1, line 1). The suppository may comprise lipids from oats (p.6, lines 19-24), galactolipids (such as digalactosyldiglycerol, DGDG at p.6, lines 12-16), glycerol (p.7, lines 16-21), water(pg 7 lines 16-19), and triglycerides (p. 6, lines 27-30) for the treatment of conditions amenable to said treatment (Claim 35). Herslof further teaches that due to the interactions between the polar and nonpolar components, the

compositions are well suited for incorporation of a pharmacologically active agent (Page 4, Lines 19-33). Herslof also teaches embodiments having varying amounts of oily triglyceride and polar lipid components where the variations affect the desired efficacy (Page 13, Table 2).

Herslof does not teach the instantly claimed component percentages of claims 9-12, 14-15 and 17, the incorporation of lidocaine.

Tomoru teaches that glycerol has long been used for the treatment of constipation, but often induces Giant Migrating Contractions (GMCs) (Page 525, Left Column, First Paragraph). To minimize unwanted GMCs caused by glycerol, Tomaru teaches administration of 5% lidocaine. (Page 525, middle of left column).

Tomoru does not teach the addition of an oily triglyceride or a polar lipid.

It would have been obvious to one of ordinary skill in the art to formulate the constipation alleviating dosage of Klaschik as a clysma, given that a clysmas is one form a dosage taught by Klaschik and to include other ingredients which are typical for rectal administration, such as those taught by Herslof.

It would have then been obvious to modify the amount of fluid present so as to optimize the amount of constipation alleviation, given that Klaschik teaches that the effect of the enema generally depends upon the amount of fluid applied.

Finally, it would have been obvious to the skilled artisan to incorporate lidocaine as the active ingredient, given that Tomoru teaches lidocaine reduces the GMCs cause by glycerol. Third, Applicants argue that there is lacking motivation to modify the solid dosage taught by Herslov into the form of an enema or clysma.

It is noted that Herslof is directed to a suppository formulation rather than an clysma formulation. Thus, when incorporating the components of Herslof into the clysma formulation taught by Klaschik, the relative percentages of the ingredients would be reduced by the addition of water as a major component of the formulation. Further, it would have been obvious to adjust the amounts of the components maximize the constipation relief provided. This includes optimizing the amount of water present, which in turn will determine the dynamic viscosity of the clysma formulation. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

While a new rejection has been made, Applicants arguments in response to the previous rejection are applicable to the new rejection and are therefore addressed as follows:

First, Applicants argue that Herslof explicitly excludes oily lipids which could be administered orally from his composition. Second, Applicants point out Herslof's composition is a combination of polar and non-polar lipids, and the non-polar lipids can be triglyceride oils but argue that pending claims 11, 12, 14, 15 and 17 exclude the presence of an oily triglyceride.

Examiner disagrees First, Applicants construe the exclusion of Herslof overly broad. Herslof states that oily lipid continuous phases which need be administered orally, such as lipid emulsions or liposomes, are outside the scope of the disclosure. Here, Herslof if not relied upon for the teaching of liposomes or lipid emulsions, but rather for the teaching of oily triglycerides, as well as the other components listed above, which are known to be included in rectally administered compositions, not orally administered.

Second, while the non-polar lipids can be triglyceride oils, they are not required to be such. The skilled artisan would find it obvious to choose from the non-polar-components taught by Herslof because they are taught to be functional equivalents. As such, where the skilled artisan chooses to use